BERNARD SANDERS
MEMBER OF CONGRESS
VERMONT, AT LARGE

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Congress of the United States

House of Representatives

Washington, DC 20515–4501

COMMITTEE ON BANKING AND FINANCIAL SERVICES

SUBCOMMITTEES:

RANKING MINORITY MEMBER:
GENERAL OVERSIGHT AND INVESTIGATIONS

DOMESTIC AND INTERNATIONAL MONETARY POLICY

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

SUBCOMMITTEES:

NATIONAL ECONOMIC GROWTH, NATURAL RESOURCES, AND REGULATORY AFFAIRS

HUMAN RESOURCES

CO-CHAIR: PROGRESSIVE CAUCUS

August 1, 2000

cc: Chris Jennings ✓
Chuck Brain

Dear John,

To follow up on our conversation, I wanted to pass along yesterday's New York Times article describing Ms. Clinton's continued support of our prescription drug reimportation legislation. As you know, this reform relates only to FDA safety approved prescription drugs. This measure will be considered as part of the Agriculture Appropriations Conference Committee's deliberations in September.

I would like to reiterate my request for a meeting with the President and the Democratic co-sponsors to discuss White House support for our bill. I look forward to hearing from you soon.

Sincerely,

Bernard Sanders
Member of Congress

The New York Times

Mrs. Clinton Faults Lazio For Stance on Drug Bill

Hillary Rodham Clinton yesterday described her opponent in the Senate race, Representative Rick A. Lazio, as beholden to the pharmaceutical industry for taking contributions from drug makers and voting against a bill to subsidize prescription drugs for the elderly.

Mrs. Clinton voiced her support for the Democrats' prescription-drug bill. She reiterated her own proposal to legalize the importing of medicine from abroad, where drugs are frequently cheaper.

"My conservative Republican opponent often says he's mainstream," she said. "But it's neither compassionate nor mainstream to leave millions of your fellow citizens without the guarantee of affordable prescription drug coverage."

Yesterday, Mr. Lazio's spokesman, Bryan Flood, denounced the Democrats' plan as a "one size fits all" approach that did not offer consumers choice. He scoffed at Mrs. Clinton's suggestion that donations from the industry had colored Mr. Lazio's views. "As a legislator, Congressman Lazio votes in the best interests of New Yorkers," he said.

Somini Sengupta (NYT)

A fax from the office of Congressman

Bernie Sanders

VERMONT - AT LARGE

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To: Mr. John Podesta

Fax #: 456-1121

From: Rep. Bernie Sanders

Date: 8/1/2000 # of Pages (Including Cover): 3

Please call 202-225-4115 regarding any problems with this transmission.

Messages:

NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
(Formerly NARD)
205 Daingerfield Road
Alexandria, VA 22314

Date: July 27, 2000

Pages including cover sheet: 8

TO: Chris Jennings

Phone:

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FROM: *John M. Rector, Sr. VP*
Government Affairs and
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If you have not received all pages, please contact
Shazia Noreen at (703) 838-2695

REMARKS: ☐ *Urgent* ☐ *For your review* ☐ *Reply ASAP* ☐ *Please Comment*

National
COMMUNITY
PHARMACISTS
Association

Formerly NARD, the National Association of Retail Druggists

N C P A
205 Daingerfield Road
Alexandria, Virginia
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phone
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July 14, 2000

Dear Senator:

On behalf of the independent pharmacists in your state, I would like to reiterate the National Community Pharmacists Associations' long standing endorsement of strongly bipartisan legislation that safely allows American consumers to benefit from international price competition for prescription medicines.

Two such landmark measures have been introduced in the Senate, The International Prescription Drug Parity Act, S.1191 and the Medicine Equity and Drug Safety Act, S.2540. These bills introduced, respectively by Senators Dorgan and Jeffords are cosponsored by Senators Snowe, Wellstone, Collins, Johnson, Gorton, Levin, and Bingaman. Similar bills are cosponsored by more than 100 members of the House of Representatives, including H.R.1885 by Representatives Berry, Emerson, and Sanders, which enjoys 92 strongly bipartisan cosponsors.

These landmark bipartisan bills are designed to permit the importation of prescription drugs by American pharmacies so long as the drugs meet Food and Drug Administration standards, including compliance with current good manufacturing practices. Such FDA-approved drugs are sold in Canada, the United Kingdom, EU countries, and other countries for prices considerably lower than the best prices available to retailers in this country. We agree with its sponsors that it "is a fair commonsense, free-market approach to lowering drug prices for constituents while benefiting small businesses" and that "it's outrageous that Americans should have to resort to crossing borders to purchase their prescriptions. We should be able to buy our medications at reasonable prices from pharmacies in our neighborhoods."

The International Prescription Drug Parity Act encourages and supports the role of pharmacists in our health care system and strengthens their ability to continue to provide affordable, critical products and services.

This bill will help assure that consumers have access to their highly trusted local pharmacist whose care and advise is essential to the appropriate use of prescription drugs, especially your elderly constituents.

The objectives of this legislation are fully compatible with the 1988, Prescription Drug Marketing Act [PL 100-293] authored by your former colleague Spark Matsunaga and the dean of the House of Representatives, Representative John Dingell. This law in an effort to prevent the importation of counterfeit or adulterated prescription drugs banned reimportation of all prescription drugs, except by manufacturers. The proposed legislation would authorize importation including reimportation by legitimate pharmacists, pharmacists buying groups and wholesalers. Further, it provides for a paper trail to assure that the drugs are properly transported and stored; and to prevent the importation of counterfeit, adulterated or other inappropriate prescription drugs. It also allows for testing of imported drugs when appropriate.

It is noteworthy that both the FDA and the PMA (now PhRMA) testified against and otherwise opposed the 1988 reimportation provision.

In addition to the strong and growing number of bipartisan cosponsors, Congress has already taken key steps in support of this critical legislation. On April 6, 2000, the Senate approved the Gorton/Jeffords Sense of the Senate resolution that the "cost disparity between identical prescription drugs sold in the United States, Canada and Mexico should be reduced or eliminated." On Monday, July 10, 2000, two relevant and significant amendments were approved by the House of Representatives on the Agriculture Appropriation bill, H.R.4461. The first amendment was approved 363 to 12. It forbids the FDA from enforcing the ban on reimportation. The second amendment was approved 370 to 12. It prevents any FDA action regarding prescription drugs manufactured in FDA approved facilities in the US, Canada and Mexico.

On Tuesday, July 11, 2000, the key bipartisan supporters of such legislation, Representatives Berry, Emerson, Sanders, Gutknecht, Dingell, Coburn, Brown (OH), and Hoekstra urged the Congress to act on this bipartisan legislation. In reference to the 2 amendments approved by the House, they observed that "By overwhelmingly supporting these amendments, the House of Representatives has made abundantly clear its desire to no longer deny American consumers access to genuine, safe, effective, FDA-approved prescription medicines that are available in the international marketplace at much lower prices."

Additionally, these key leaders on this issue stressed that "While the House remains divided along party lines in its effort to provide Medicare beneficiaries with prescription drug coverage, it would be truly unfortunate to see the House of Representatives squander this extremely bipartisan, and almost unanimous, will of its Members to responsibly deal with this issue."

The small businesses, independent health care professionals we represent are the preferred choice of American consumers. Our members function in the market in a variety of forms. They do business as single stores ranging from apothecaries to full line high volume pharmacies; as independent chains (e.g. 100 pharmacies) and as franchises (e.g. Medicine Shoppe, 1200 pharmacies). Whatever the form of business entity, however, independent pharmacists are the decision makers for this wide variety of NCPA member companies.

The most in depth consumer survey to date conducted by Consumer Reports, involving 15,000 consumers, published last fall, found that consumers preferred independently owned pharmacies for several reasons:

> Independents provided more personal attention
>
> Independents provided more useful information about both prescription and nonprescription drugs
>
> Independent druggists were seen as more professional, more sensitive to families' needs, and easier to talk to
>
> Independents kept consumers waiting less time for drugs, had prescriptions ready for pickup more often, and provided out-of-stock medicine faster

Our 1200 plus independently owned members in the Medicine Shoppes franchise were ranked second; the supermarket drugstores were third, the mass merchandisers were fourth; and the worst stores overall were the big corporate run chains. No preference was expressed for mail order.

The community pharmacist of today is simultaneously a health care professional and a small businessperson. As owners, managers, and employees of independent pharmacies, our member's 30,000 pharmacies and our 75,000 are committed to legislative and regulatory initiatives, which are designed to protect the public; to provide them a level playing field and a fair chance to compete; and to provide quality pharmacists services to your constituents. The International Prescription Drug Parity Act and the Medicine Equity and Drug Safety Act meet each of these criteria.

We urge the HELP and the Appropriation Committees and the Senate leadership to take steps necessary to assure the enactment in the 106th Congress of this long overdue pro-consumer, pro-competitive legislation.

Warm Regards,

John M. Rector
Senior Vice President
Government Affairs and
General Counsel

EQUAL™ ACCESS

National COMMUNITY PHARMACISTS Association

LEGISLATIVE DEFENSE FUND

205 Daingerfield Road ★ Alexandria, Virginia 22314-2885

JEFFORDS/DORGAN IMPORT AMENDMENT APPROVED 74 – 21

Date: July 24, 2000

To: NCPA Legislative Committee and Friends of Independent Pharmacy

From: John M. Rector, General Counsel

By nearly a 4 to 1 margin, the United States Senate approved the Jeffords/Dorgan amendment to the FDA Approp – H.R.4461, to permit pharmacists and wholesalers to import safe FDA approved Rx drugs from other countries. The debate on the amendment cosponsored by Wellstone (D-MN), Snowe (R-ME), Gorton (R-WA), Johnson (D-SD), Levin (D-MI), Bryan (D-NV), and Gregg (R-NH) lasted more than three hours.

The proponent speeches by Jeffords (R-VT), Dorgan (D-ND), Gorton (R-WA) and Johnson (D-SD) were outstanding. The full text of the July 19, 2000 is available at **http://thomas.loc.gov/r106/r106s19jy0.html** Drug maker main allies opposing the bipartisan amendment were Senators Breaux (D-LA), Hatch (R-UT), and Frist (R-TN). Breaux, for example made an unconvincing argument about having been hoodwinked by Hong-Kong vendors when he paid $5.00 for a LaCoste shirt. He also stressed that there was no guarantee that consumers would see any benefit from lower pharmacist acquisition costs. Frist whose family business is HCA Columbia, the "so-called" managed care giant, cited former Hatch staffer and FDA head, Kesslers' and former FDA head, Goyans' opposition.

Frist conveniently failed to mention that Kessler's record on PDMA import issues was at best lackluster and that FDA and then PMA opposed what is now current law. Lastly, he failed to disclose that Goyan has in recent years been CEO of one drug company, Chairman of the Board of another and Director for several more drug makers. Hatch commended Jeffords and Dorgan for "protecting some of the gaps and shortcomings related to drug "safety in the companion bill which the House passed 370 to 12. However, he strongly opposed the amendment. He was able to cite a very creative letter from NWDA opposing Jeffords/Dorgan. In fact, Hatch said the wholesalers "Beg us not to pass this type of legislation because of the harm it could cause to the American public and to the American consumer." NWDA even claimed that the "financial responsibility of some wholesaler could be jeopardized if the Jeffords measure were to be enacted."

Regarding NWDA's "sky is falling" rhetoric, it is important to remember that the amendment does not require a wholesaler to take advantage of the new import authority. I imagine, many of our independent buying groups, independent wholesaler, cooperatives, and independent chains alike would be pleased if the large NWDA members declined to take advantage of lower acquisition costs. Since NWDA gave opponents a place to stand other than defending drug maker pricing practices, it was uncertain what impact their opposition would have in the Senate. I prepared an amendment to limit wholesaler access to those who have less than 5% market share. Fortunately, the NWDA approach was rejected 4 to 1 and the 5% amendment was not necessary.

Next, there will be a House/Senate conference. The Senate conferees have been appointed and they are all the members of the Agriculture Appropriation Subcommittee plus Committee chairman Stevens (R-AK) and ranking member Byrd (D-WV). The House conferees have not yet been appointed, but they are likely to include the House Subcommittee members and leadership of the full Committee. Enclosed you will find a variety of materials including the 74 to 21 Roll Call vote, the Senate/House Appropriation members, my letter to the Senate, some key House Dear Colleague letters, and our legislative priorities for the 106th Congress.

It is the general view that something on imports will become law. Each of you need to contact your two Senators and your Representative with special emphasis on Appropriation Committee members to support at least the Jeffords/Dorgan approach or any bipartisan solution that will permit pharmacists, pharmacist buying groups, independent chains, cooperatives, and independent wholesalers to import FDA approved Rx drugs.

More to come...

National COMMUNITY PHARMACISTS Association

LEGISLATIVE DEFENSE FUND

205 Daingerfield Road ★ Alexandria, Virginia 22314-2885

BULLETIN

Date: July 11, 2000

To: NCPA Legislative Committee Members and Friends of Community Pharmacy

From: John M. Rector, General Counsel

Re: H.R.1885 – The International Prescription Drug Parity Act

Great progress has been made on another of our top priorities for the 106th Congress. On June 28th, after the 217 to 214 vote on the Merck/Medicare bill, the House debated importation of Rx drugs. Although the Rules Committee prevented a vote on H.R.1885, the hour long plus debate and approval of the Gutknecht amendment, which shifts to FDA the burden of proof under current import law, has helped lay the groundwork for real progress on H.R.1885.

New cosponsors are added every day, which now number a strong bipartisan 92. The 6/28/00 debate provided evidence that dean of the House and author of the PDMA, John Dingell sees conflict between the PDMA he authored in 1987, which prohibits reimportation to target counterfeit and adulterated Rx drugs and a new law to enable pharmacists to import Rx drugs. PhRMA and its' allies, e.g. former Commissioner Kessler and Goyan have argued that amended PDMA to allow legitimate pharmacies to import legitimate Rx drugs would threaten the safety of American consumers.

Last night, the House amended the FDA Appropriations bill to prevent FDA from enforcing the reimportation ban by 363 to 12 (Crowley) and to prevent FDA from taking any action on importation (or reimportation) from US, Canada or Mexico by 370 to 12 (Coburn-Baldacci).

This evening the four key Republican and four key Democratic members on this issue requested urgent action by the Commerce Committee on H.R.1885. Their 7/11/00 letter and our letter to each member of the House of Representatives is enclosed. It is increasingly likely that H.R.1885 can become law this session.

DATE: 7/31/00

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ROOM 405H, HUMPHREY BUILDING
200 INDEPENDENCE AVE, SW
WASHINGTON, D.C. 20201

PHONE: (202)690-7450 *FAX: (202)690-8425*

Please give copy to Chris Tom R. Matt V

TO: Jeanne Lambrew

OFFICE: _____

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Dingell letter

(INCLUDING COVER): 16

REMARKS:

FROM:

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[ ] PATTI BRANDT
[ ] SHARON CLARKIN
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[ ]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 25 2000

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Dingell:

Thank you for your continued interest in the safety of prescription drugs available in the United States. This is in response to your letter of July 14, 2000, expressing your concern that two amendments recently adopted by the House of Representatives to the Agriculture Appropriations bill could seriously undermine the Prescription Drug Marketing Act (PDMA), and thus adversely affect public health. Specifically, you refer to amendments offered by Representatives Crowley and Coburn. You also referenced in your questions H.R. 3240, a bill passed by the House of Representatives, sponsored by Representative Gutknecht.

The Food and Drug Administration (FDA or the Agency) shares your concerns. We understand and are sympathetic to the Members' concerns about the high cost of prescription drugs, particularly for our nation's seniors. However, because of the significant impact these amendments will have on FDA's ability to protect the public health, they are not the appropriate solution to the drug pricing problem. The remedy to the drug-pricing problem should not be at the expense of safety.

You asked specific questions about the amendments. Your questions will be restated, followed by our response.

1. **Please provide a detailed analysis on how (H.R. 4461 and H.R. 3240) would affect FDA's present operations regarding efforts to prevent misbranded or potentially dangerous drugs from entering the U.S. Specifically, please provide:**

a. a description of how the present system now used by FDA works;
b. what the present system is intended to accomplish; and,
c. what changes would be required (and the potential effects of those changes) if this legislation passes in its present form.

Please include a discussion of how these amendments would affect the activities of other agencies, such as the U.S. Customs Service, with responsibilities for assuring the safety of imported prescription drugs.

Section 801 of the Federal Food, Drug and Cosmetic Act (FD&C Act or the Act) gives FDA the authority to refuse a product if it appears from the examination of samples or otherwise, to violate certain provisions of the FD&C Act, for example, if the product is adulterated, misbranded or unapproved. This enables our FDA investigators and U.S. Customs Service (Customs) officials to process entries efficiently. This was true back in 1906 when section 801 was first enacted and it is more salient today when products move freely around the world, facilitated by our expanded global market, the Internet, and trade agreements.

Under FDA's regulations, if a product appears as though it may be in violation of various statutory provisions it is subject to refusal of admission into the U.S. a Notice of Detention is sent to the importer, and the importer has the right to present evidence to FDA. Evidence may be submitted to FDA to demonstrate that the product they are offering for import: 1) does not appear to be violative, 2) is not a product that is subject to the Act, or, 3) may be reconditioned or relabeled and thus brought into compliance with the Act. Subsequent to refusal, section 801 gives the importer the opportunity to re-export the product.

Products entering the U.S. can be roughly grouped into three categories: commercial shipments, air couriers and mail deliveries, and personal baggage of individuals physically crossing the borders. Practically, the system works as follows:

Shipments of products imported for Commercial Distribution

When shipments of FDA-regulated products are imported for commercial distribution, the importer (or the importers' customhouse broker) submits entry and invoice data to FDA,

either electronically via Customs' ACS system, or via paper entry documents. FDA reviews the entry data for each shipment. Based on this "on screen" or paper review, FDA decides whether to allow the shipment to proceed without examination, to collect a sample for FDA lab analysis, or to detain the product pending a refusal decision based upon the appearance of a violation. If FDA lab analysis determines that the product complies with FDA requirements, the product is released; otherwise it is detained based on the results of the lab analysis. (FDA does limited testing for potency and identification. Under section 801(d)(1) it has not been necessary to test for authenticity as only the manufacturer may import into the United States.)

When a product is detained, a Notice of Detention is issued, and the importer is offered the opportunity to present evidence to FDA. If the evidence presented is sufficient to overcome the appearance of the violation, the product is released, and the importer may distribute it in domestic commerce. If the importer's evidence is not sufficient to overcome the appearance of a violation, the product is refused admission and must be exported or destroyed within 90 days.

Shipment of products for personal use imported via air express couriers

These shipments are processed similarly to commercial shipments except that FDA is notified of the entry by the air express courier rather than the importer. Based on the entry information supplied, FDA either allows the product to proceed without examination, or detains. Because of the normally lower value and larger number of such entries, it is relatively rare that FDA will physically sample and/or examine such entries. As is the case for commercial entries, FDA issues a Notice of Detention and gives the importer the opportunity to present evidence. If the importer presents sufficient evidence, admission and the product is released; otherwise it is refused must be exported or destroyed within 90 days.

Shipments of products for personal use imported via international mail

Mail shipments carried by the U.S. Postal Service are fundamentally different from commercial shipments or air express shipments. FDA does not receive any entry information

and depends upon Customs inspectors to identify mail entries of FDA-regulated products from and set them aside for FDA examination. Customs inspectors x-ray packages thought to contain FDA-regulated product, and if the x-ray indicates that the package does contain an FDA-regulated product the Customs Inspector opens the package and sets it aside for FDA examination. If an FDA Investigator determines that the article is in compliance with the applicable law and regulations it is sent on to the addressee. If the article appears to be subject to refusal, the addressee is sent a Notice of Detention, stating the reason why the article appears to be refusable, and informing the addressee of the right to contest FDA's decision. If the addressee fails to provide sufficient evidence or chooses not to reply the article is refused admission and either returned to the foreign sender (if it bears a valid return address) or it is destroyed.

"Warning Notices"

FDA has a history (dating back to at least the mid 1950s) of allowing humanitarian access to such products provided that such access does not pose an unreasonable risk to the public health. Initially, this practice was begun for foreign nationals on medication travelling in the U.S. or U.S. travelers who became ill while out of the country, so that they could bring in enough "urgent" supply to finish the course of the medication. It was expanded in the 1980s when no treatments were available in the U.S. for AIDS and some with possible promise were available in other countries. When an FDA Investigator exercises his or her enforcement discretion (under FDA's Personal Import Guidance) to release such a product to the importer, it may be "Released with Comment" stating that the product appears to fail to meet the relevant U.S. standard. In addition, a notice in the form of a letter may be attached to the shipment, alerting the importer that FDA cannot vouch for the safety or efficacy of the product. Although characterized as a "Warning Notice," this notice is in effect an attempt to provide the importer with information regarding the possible dangers posed by use of the product.

c. what changes would be required (and the potential effects of those changes) if this legislation passes in its present form.

H.R. 4461 (Amendments by Representatives Crowley and Coburn)

Both of the amendments prohibit FDA from expending funds to enforce section 801(d)(1). Under section 801(d)(1), no prescription or insulin-containing drugs manufactured in a state and exported may be reimported by anyone other than the manufacturer. Section 801(d)(1), in essence, codifies a presumption that U.S. manufactured drugs that are exported out of the U.S. and then imported back to the U.S., are adulterated, misbranded, or otherwise subject to refusal unless they are imported by the manufacturer. Under the Crowley amendment, anyone could reimport such drugs into the U.S., and FDA would have to take the added step of acquiring evidence that these drugs are adulterated, misbranded, or counterfeited. Removing the presumption of section 801(d)(1) would thus endanger the health and safety of Americans by placing an added evidentiary burden on an already overburdened FDA. Per the terms of the amendment, FDA would no longer be able to refuse the drugs as violative of 801(d)(1).

The Coburn amendment goes even further. It prohibits FDA from interfering with the importation of an approved product manufactured in Mexico, Canada, or the U.S. for any reason in any way. Thus if a routine inspection of a Mexican or Canadian firm producing an approved drug reveals good manufacturing practices (GMP), labeling, or other problems, FDA would be completely prohibited from interfering with the importation of that product. The Coburn prohibition extends not only to FDA's refusing the product at the border but also to FDA's taking of any other action that would interfere with its importation.

Thus, if an importer merely alleges that a product offered for import falls under the terms of the Coburn amendment, FDA would be prohibited from investigating the truth of importer's assertion or anything else about the product because, if the importer is correct, FDA's mere act of investigating the product would have interfered with importation of the product and would thus have violated the Coburn amendment. One could even argue that FDA could not even ask Customs to forward information about such products to FDA for review since merely expending effort in reviewing the information would interfere with the product's importation.

Once the product is imported, it is conceivable that FDA would be prohibited from pursuing a domestic enforcement action against the product under the Coburn amendment as well. Any domestic action could be construed as interfering with

subsequent importations of the same product and thus would be prohibited by the Coburn amendment. Even FDA's practice of sending informational letters to purchasers of drugs through the Internet could be construed as interfering with the product's importation and thus would be prohibited by the Coburn amendment. Finally, one could even make the argument that under the expansive language of the Coburn amendment, FDA could not withdraw approval of the product because that would interfere with the importation of a product that was approved at one time.

The expansive language of Coburn could also extend its application unintentionally to products from countries other than Mexico, Canada, and the U.S. Importers of drugs manufactured in other countries may have two possible means of gaining the pervasive protection of this amendment. First, as mentioned above, if an importer merely alleges that its product meets the terms of the Coburn amendment, FDA would be prohibited from investigating the truth of that assertion or taking any other action that would interfere with its importation lest the importer be found to have been right. Second, other parties to the General Agreement on Tariffs and Trade (GATT) may be able to argue that the preference given to Mexican and Canadian products outside the terms of a free trade agreement violates the GATT so that all other GATT members are entitled to similar treatment.

Seen in this light, the Coburn amendment could insulate any imported prescription drug from any FDA enforcement action no matter how dire a health or safety violation occurs. This would clearly have a devastating potential effect on consumer health and safety because FDA would be powerless to protect the public against any such threat that would arise.

Both of these amendments compromise the safety system designed to protect the American public from drugs that do not meet the standards of the FD&C Act.

H.R. 3240, "Drug Import Fairness Act of 2000"

As we understand it, the intent of this bill is to change the way in which the Agency issues warning notices for possibly violative products offered for import. We understand the intention is to provide the importer with more specific information about the nature of the possible violation.

However, as drafted, the bill extends far beyond this narrow objective. One key problem is that the term "warning notice" is defined so broadly in the bill that it arguably includes FDA's routine Notices of Detention. These notices are key legal documents that FDA must issue to importers when FDA believes drugs may "appear" violative in order to provide adequate notice to the importer of the FDA's pending decision. Therefore, they are designed to accommodate due process requirements prior to FDA taking final action on the product through refusal or admission. They inform the importers of what their options are and how they may wish to proceed to obtain release and avoid a refusal. By changing the criteria for these notices, the bill imposes an unnecessary burden on FDA with little benefit to the consumer.

More importantly, however, the bill would prevent FDA from refusing a product that appears to be restricted or prohibited in the country of origin or that appears to violate other Federal law such as medical device GMPs. FDA would have to prove the actual existence of a restriction, prohibition, or other violation before even sending the initial detention notice.

Nevertheless, in response to the interest in providing additional information to importers about the nature of the possible violation, the Agency is considering changes we might be able to make to our warning notices and notices of detention without unduly burdening the import screening process.

2. **Please determine if either of these amendments would have any effect on FDA's ability to enforce good manufacturing practices (GMPs) in any foreign firms that ship drugs to the U.S. If so, please explain any potential effect on consumer health and safety.**

As we read the amendments, they would have a devastating effect on FDA's ability to enforce GMPs in any foreign firms that ship drugs to the U.S. Currently, when FDA discovers GMP violations in foreign plants, it shares that information with FDA's District Offices thereby enabling them to refuse admission of any affected products shipped from that plant in the absence of any ameliorating evidence. This process is efficient, fair, and effective. As described above, the amendments would prohibit FDA from using this or any other means of interfering with the importation of drug products that do not comply with FDA's GMP requirements. Also this

would clearly have a devastating potential effect on consumer health and safety because FDA would be powerless to protect the public against any such threat that would arise.

3. Please provide a full description regarding what a "warning letter" is and how it is typically used by the FDA. Please compare this with correspondence that is sent by Customs.

Several different FDA written communications can fall under the description of "warning letters." We believe that the communication that is the subject of Representative Gutknecht's bill is a informational letter issued to individuals when granting imports under the Agency's personal importation policy.

The more usual FDA communication is a "Notice of FDA Action," that provides any importer (whether importing a product for personal or commercial purposes) the legal notice of FDA's pending admissibility decision, under section 801. This notice has two functions: to inform the importer of the reason why FDA believes the product may be refused admission, and to afford the opportunity for the importer to introduce evidence to the contrary. It describes the product and states the relevant violation (e.g., unapproved new drug, misbranded new drug, adulterated drug, etc.). Finally, it informs the importer of the right to introduce testimony to FDA regarding the admissibility of the product, as we have described above. A copy of this form is enclosed for your information.

For individuals crossing a border, as referenced above, the Agency provides the person with a second type of notice, which is called a "Dear Consumer" letter or "warning notice." This could more correctly be characterized as a "consumer information letter" rather than a "warning letter." The purpose of this letter is to advise the individual of the possible risks that may be associated with an unapproved product. When FDA exercises its enforcement discretion to permit individuals to import a 3-month supply of certain drugs for personal use, the "Dear Consumer" letter is our way of informing those individuals about the risks of importing such products. Specifically, the letter informs individuals that the imported drugs may be unapproved, adulterated or misbranded, and informs of the possible health consequences of taking such drugs. The letter also describes the law for importing unapproved products. A copy of this "Dear Consumer" letter also is enclosed.

4. It appears that these amendments would directly affect the ability of FDA to send warning letters to consumers that purchase drugs over the Internet. As you know, some web sites appear to be covertly linked to foreign drug suppliers. When a consumer orders from such a site, it is not always obvious that they are dealing with an offshore supplier, and thus a potentially non-FDA approved facility. Often, warning letters may be the only indication that the Internet-ordered drugs originated from a foreign (and potentially dubious) source. Please indicate how this legislation could affect FDA's ability to protect consumers who purchased drugs in this way.

As we read these amendments and the bill, the effect for drugs purchased over the Internet would be the same as all others. FDA's issuing these letters could be construed to constitute interference with imports covered by the Coburn amendment. Thus, FDA would be prohibited from expending funds to send these letters. Offshore importers who market to U.S. citizens could merely allege that these products meet the terms of the amendments and thus potentially completely insulate these shipments from FDA oversight. Opportunistic criminals may introduce counterfeit drugs into the U.S. by disguising them as approved U.S. pharmaceuticals. Unless such drugs could be proven counterfeit at the port of entry, which is a nearly impossible task, the Agency would be forced to admit them under this amendment, even if investigators could legitimately demonstrate that the drugs appeared to be counterfeit.

The Internet vastly amplifies the manner in which products may be purchased from foreign sources and shipped to the U.S.

5. Please detail any other potential effects this legislation could have on FDA's ability to protect consumers from potentially dangerous drugs that originate abroad.

These amendments will likely encourage the very sources of adulterated, misbranded, and unapproved drugs that were cut off by section 801(d)(1), to begin shipping again. FDA, with its limited resources, would be extremely hard-pressed to do the investigative work necessary to discover and stop these new sources of potentially harmful products.

6. Finally, please provide technical assistance in the form of specific suggestions for legislative or regulatory changes that would be needed in order to facilitate the safe

importation of prescription drugs by individuals, wholesalers, or retailers.

As you mentioned in your letter that "PDMA was designed to restore the integrity and control over the pharmaceutical market necessary to eliminate both the actual and potential health and safety problems before injury to the consumer could occur." You further state in your extension of remarks attached to your letter, "...legislation to modify the PDMA in a responsible fashion is an idea whose time has come."

We would be happy to provide technical assistance to you or your staff as you consider appropriate legislation.

In some of your questions, you asked that we provide information about the practices of or impact on the U.S. Customs Service. Rather than respond on Customs' behalf, I have taken the liberty of forwarding your letter to Customs' for reply.

Thank you for your interest in this matter. We look forward to working with you to continue to provide a system of safety that the American public has come to expect and deserve. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosures

cc: The Honorable Thomas J. Bliley, Jr.
Chairman
Committee on Commerce
House of Representatives

U.S. Food & Drug Administration

Baltimore District Office

Notice of FDA Action

Entry Number: [redacted]
Reference No : [redacted]
Port of Entry: 5401, Washington D.C., DC

Notice Number: 1
June 26, 2000

[redacted]

Shipper: unknown
unknown
unknown
Unknown Country [redacted]

A mail shipment addressed to you from a foreign country is being held by the post office at the request of the Food and Drug Administration (FDA).

Summary of Current Status of Individual Lines

No.	Product Description	Quantity	Current Status
001	GEROVITAL.GH3	100 Tablets	Detained 06-26-2000

The shipment may also contain other items not listed above.

DETAINED

The following products are subject to refusal of admission into the United States under authority of the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to in violation as indicated below:

No.	Product Description		Respond By
001	GEROVITAL.GH3	100 Tablets	

July 17, 2000

FD&CA Section 505(a), 801(a)(3), UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application.

Notice of FDA Action
Entry Number: [redacted]

Notice Number: 1
Page: 2

All products of this kind must meet the requirements of the Federal Food Drug and Cosmetic Act or other laws enforced by the U.S. Food and Drug Administration. These laws are designed to protect you from, among other things, unsafe or misrepresented foods, drugs, biologics, cosmetics, devices, and other articles. These products do not appear to comply with the law.

Please direct your response to:
[redacted] Compliance Officer
U.S. Food & Drug Administration
[redacted]
(410)962-3590 [redacted]
(410)962-2219 (FAX)
[redacted]

This Notice does not in any manner accuse you of violating any law.

If you have a good reason to believe that the products comply with the law and wish to discuss it with us, you may come personally to this office or write to us. You must provide the entry number shown on the upper left of this notice whenever communicating with us.

Please direct your response to:
[redacted] Compliance Officer
U.S. Food & Drug Administration
~~2100 Broening Hwy~~ 900 Madison Ave.
Baltimore, MD ~~21224~~ 21201
(410)962-3590 [redacted]
(410)962-2219 (FAX)
[redacted]

If you do not wish to claim this shipment, you may disregard this notice and the shipment will be returned to sender without cost to you. The shipment will be returned automatically if we don't hear from you.

Notice of FDA Action
Entry Number: ---[redacted]

Notice Number: 1
Page: 3

The shipment may contain items not included in this notice. If any portion of this shipment is refused admission, the U.S. Customs Service will cause the entire shipment to be returned to the sender or destroyed if the sender is unknown.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

Dear Consumer:

This letter is to advise you that the Minneapolis District of the United States Food and Drug Administration (FDA) has examined a package addressed to you containing drugs which appear to be unapproved for use in the United States.

The United States Federal Food, Drug and Cosmetic Act (the Act) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act. Unapproved new drugs are any drugs--including foreign-made versions of U.S. approved drugs--that have not been manufactured in accordance with and pursuant to an FDA approval. Under the Act, FDA may refuse admission to any drug that "appears" to be unapproved, placing the burden on the importer to prove that the drug sought to be imported is in fact approved by FDA. Absent evidence that the specific drugs sought to be imported from a foreign country have been manufactured pursuant to an approved new drug application, in the manufacturing facility permitted under the application, such drugs would appear to be unapproved new drugs subject to FDA enforcement action.

We appreciate that there is a significant cost differential between drugs available here and those in other countries. However, many drugs sold in foreign countries as "foreign versions" of approved prescription drugs sold in the United States are often of unknown quality with inadequate directions for use and may pose a risk to the patient's health. FDA approves a drug on the basis of scientific data proving it to be safe and effective. FDA approved labeling provides information on how and when the drug can be used to maximize effectiveness and minimize any harmful side effects. The manufacturing facilities and procedures for approved products are also carefully regulated by FDA to ensure product integrity. Since FDA cannot assure you the drug purchased in the foreign country would be the same product your physician's prescription is written for, we recommend the product covered by the prescription be acquired in the United States.

Because you are taking this medication under the care of a physician and we do not want to cause your medical treatment to be unduly affected, we are releasing this shipment. However, future shipments of these or similar drugs may be refused admission.

DATE: 9-7-00

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 INDEPENDENCE AVE., SW
WASHINGTON, D.C. 20201

PHONE: (202) 690-7627 **FAX: (202) 690-7380**

OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
ROOM 416-G HUMPHREY BUILDING

FROM: Chris Jenning

TO : Jeanne Lambrew

OFFICE : _____

PHONE NO : _____

FAX NO : 456-5557

TOTAL PAGES
(INCLUDING COVER) : _____

[X] RICHARD J. TARPLIN
[ ] KEVIN BURKE
[ ] AQUILA POWELL
[ ] ROSE CLEMENT LUSI
[ ] FRANKIE MELTON
[ ] EDWARD WHITLEY

REMARKS:

Per our conversations.
DES has signed off.
Rick

]DRAFT LETTER TO AGRICULTURE APPROPS CONFEREES/Revised/9/7/00

Conferees:

I want to take this opportunity to express the Administration's views on three amendments dealing with the Food and Drug Administration's (FDA) authority over the importation of prescription drugs that were added to the House and Senate versions of H.R. 4461, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001. All three amendments affect Section 801 of the Food, Drug and Cosmetic Act (FD&C Act), and reflect the concern of many members of Congress with the high cost of prescription drugs.

As you know, this Administration is deeply concerned about the high cost of prescription drugs, and we applaud the bipartisan efforts of those in both Houses of Congress who have sought innovative solutions to this problem. We know that lack of access to affordable medicines in this country has left many Americans with no option other than to go abroad to obtain affordable prescription drugs. This situation is unacceptable and it is one reason why the Administration has proposed a voluntary Medicare prescription drug benefit that is affordable and accessible for older Americans and people with disabilities.

At the same time, we must also recognize that the importation of prescription drugs is only one element of a broader challenge FDA faces in dealing with new practices for the marketing and sale of prescription medicines. Recent congressional hearings have raised concerns about counterfeit drugs entering the U.S., and about the safety and efficacy of drugs sold over the Internet. As we work with Congress on ways to make prescription drugs more affordable, we also want to make sure that FDA has the statutory authority and budgetary resources necessary to ensure the American public's health and safety in a global business environment. In this regard, we hope the Congress will act favorably on the Administration's request for $10 million in FY 2001 funds specifically to ensure that Internet sites are operating legally and do not jeopardize patient safety.

With respect to the specific amendments to H.R. 4461, let me first address the Senate amendment sponsored by Senators Jeffords, Dorgan, and others, and modified by Senator Cochran.

We appreciate the Senators' commitment to making prescription drugs more affordable, and the extraordinary efforts that they made to address our health and safety concerns with earlier versions of the legislation. We also appreciate the leadership of their House counterparts,

Representatives Berry, Sanders, and Emerson, in this regard. As you know, the Jeffords et.al. provision would specifically authorize wholesalers and pharmacists to reimport or import FDA approved prescription drugs. Unlike the two House amendments discussed below, this provision includes extensive procedural safeguards for American consumers through a system of tracking drug pedigree and testing product authenticity and degradation. However,the key to the success of this new system is for Congress to provide full funding to implement the program. FDA has estimated that it would cost approximately $23 million in the first year to establish the new system and in excess of $80 million per year, when fully implemented. If our already resource-strapped FDA is not provided with the necessary additive funding to implement and oversee this change in law, the borders would effectively be opened with no gatekeeper to provide protection from harm.

As modified by Senator Cochran, the Jeffords amendment also stipulates that the new system will not become effective until the Secretary of Health and Human Services certifies that 1) there is no (greater) risk to public health and safety and 2) that the new system will result in a significant reduction in costs for the U.S. consumer. As Secretary of HHS, I feel obligated to inform you that I would not be able to certify that there is no increased risk to public health and safety unless new and sufficient

resources were provided to implement the new safety system envisioned in the Jeffords amendment. These must be new resources, not funds already dedicated in either bill to the FDA's core functions or to priority initiatives.

We also do not believe it is possible to prospectively make the certifications required by the Cochran amendment. The new safety system in the Jeffords amendment would first have to be implemented in order to generate the necessary data upon which to base the certification determinations.

The House-passed version of H.R. 4461 incorporates two amendments that do not contain the procedural safeguards of the Jeffords amendment and that, in fact, would severely restrict the authority of the FDA to enforce existing law with respect to the importation of prescription drugs. The Administration strongly objects to these amendments because they could threaten public health and safety, and might result in consumers purchasing drugs that are counterfeit, mislabeled or otherwise adulterated.

These two amendments, sponsored by Representatives Crowley (D-NY) and Coburn (R-OK), would prohibit FDA from expending funds to enforce section 801(d)(1) of the FD&C Act. Under section 801(d)(1), no prescription or insulin-containing drugs manufactured in a state and exported may be reimported by anyone other than the manufacturer. This provision - the

Prescription Drug Marketing Act - was enacted by Congress, after two years of hearings and investigations, to protect the public from prescription drugs that may be improperly stored and handled abroad, and to reduce opportunities for importation of counterfeit and unapproved prescription drugs. Prohibiting expenditure of any funds to enforce this section, especially in the absence of the procedural safeguards included in the Jeffords Senate amendment, could reopen the door to all of the previous abuses that Congress sought to prohibit by enacting section 801(d)(1).

Under the amendments, FDA would have restricted ability to prevent entry of drugs suspected of being adulterated, misbranded, or counterfeited, thus endangering the health and safety of Americans. Moreover, under the Coburn amendment, FDA would not be allowed to interfere with the importation of FDA-approved drugs from Mexico or Canada, even in the case of a demonstrated serious public health and safety problem. For example, it would prohibit FDA from excluding approved drugs manufactured in Mexican or Canadian facilities that are adulterated because of manufacturing discrepancies or that are inadequately labeled. It is not clear whether this type of regulatory preference, even if it were part of a free trade agreement, would be a permitted exception to the most-favored-nation obligation of the General Agreement on Tariffs and Trade. Therefore, this raises the specter of the U.S. having to accord the same

treatment for drugs imported from every other World Trade Organization member.

In closing, let me reiterate the Administration's desire to work with the Congress to make prescription drugs more affordable and accessible through a voluntary Medicare prescription drug benefit. With respect to the three amendments to H.R. 4461 now in conference, we believe the Jeffords amendment represents a promising approach, but it can only be effective if Congress provides new and sufficient resources. We strongly oppose the two House importation amendments that we believe could compromise public health and safety.

Thank you very much for your consideration of our views.

Sincerely,

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